

***Remarks***

Reconsideration of this Application is respectfully requested.

Applicants respectfully request that the Office acknowledge its consideration of the First Supplemental Information Disclosure Statement ("First Supplemental IDS") filed on February 26, 2004 by initialing and signing the Form PTO-1449's submitted therewith, and returning the signed forms to Applicants' representative.

Upon entry of the foregoing amendment, claims 1-15 are pending in the application, with claims 1, 9, and 12 being the independent claims.

The title has been amended to delete the superfluous "New Prostate Cancer Antigen" recitation and to refer to "PCA3". The amendments to the claims have been done to clarify the invention, and support for such amendments can be found in the originally filed claims and throughout the specification.

Applicants thank the Examiner for the rejoining of all claims and inventions.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Rejections under 35 U.S.C. § 102***

***Rejection Under 35 U.S.C. § 102(a)***

The rejection of claims 1-7 and 11 under 35 U.S.C. § 102(a), as allegedly being anticipated by Verhaegh *et al.*, *J. Biol. Chem.* 275:37496-37503 (2000) ("Verhaegh") is respectfully traversed.

Applicants respectfully assert that the use of Verhaegh as a reference under 35 U.S.C. § 102(a) is not proper as Verhaegh is the Applicants' own work. Verhaegh was published in the December 2000 issue of *The Journal of Biological Chemistry* (Volume

275) less than one year before November 2001, the filing date of the instant application. Verhaegh was also published less than one year before the filing dates of the priority applications: Japanese Appl. No. 2001-164963, filed May 31, 2001, and Canadian Patent Appl. No. 2,357,073, filed September 7, 2001.

Verhaegh cannot qualify as a prior art reference under 35 U.S.C. § 102(a) because Verhaegh is Applicants' disclosure of their own work. Although Verhaegh lists co-authors in addition to Applicants, a rejection under 35 U.S.C. § 102(a) may still be overcome by establishing that the portions of the reference pertinent to the claimed invention describe Applicants' own work. *See In re Katz*, 215 U.S.P.Q. 14 (C.C.P.A. 1982). In the Declaration under 37 C.F.R. § 1.132 ("Declaration"), attached as Exhibit A, Applicant Jack Schalken states that co-authors Adrie van Bokhoven and Frank Smit performed experiments disclosed in the Verhaegh document that do not amount to an inventive contribution of the claimed invention of the present application. As stated in the Declaration, Adrie van Bokhoven and Frank Smit were technicians in Dr. Schalken's laboratory and carried out experiments under Dr. Schalken's direct supervision and control.

Thus, in light of the Declaration, Verhaegh cannot serve as a prior art reference in a rejection of the pending claims under 35 U.S.C. § 103(a). Accordingly, withdrawal of the rejection under 35 U.S.C. § 102(a) is respectfully requested.

***Rejection Under 35 U.S.C. § 102(b)***

The rejection of claims 1-6 under 35 U.S.C. § 102(b) as allegedly being anticipated by Bussemakers *et al.*, *Cancer Res.* 59:5975-5979 (1999) ("Bussemakers") is respectfully traversed.

The Office alleges that the genomic map of DD3 shown in Fig. 3 of Bussemakers, which does not show any sequence, "inherently contains the nucleic acids of instant claims 1 and 2." The Office further alleges that page 5976 of Bussemakers also anticipates vector claims 3 and 4, and that, inherently, claims 5 and 6 are also anticipated. Applicants respectfully disagree.

Bussemakers does not teach or suggest the nucleic acid sequences recited in claims 1 or 2. These promoter sequences had not been characterized physically or by sequence prior to the present invention. Supporting this contention is Bussemakers at page 5979, left column, last sentence: "[I]ikewise, the DD3 gene promoter needs to be characterized."

Clearly, therefore, the promoter and regulatory sequences had not been identified and characterized in Bussemakers.

Further, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference. MPEP § 2112. In relying upon the theory of inherency, the Office must provide a basis to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the alleged prior art. MPEP § 2112.

The genomic map of DD3 set forth in Bussemakers does not necessarily disclose the sequences claimed in the present applicaiton. There is no indication, via extrinsic evidence or otherwise, that the sequences are disclosed. In fact, as discussed below, the extrinsic evidence indicates otherwise.

Bussemakers discloses two GeneBank accession numbers. Separate blasts of AF103908 and AF103907 (see p 5977, left column) failed to show any homology with the claimed sequences of the instant invention. Clearly Bussemakers does not anticipate,

inherently or otherwise, the claimed invention because the sequences taught in Bussemakers are not claimed in the present invention.

Based on the foregoing, vector claims 3 and 4 and cell claims 5 and 6 are also not anticipated by Bussemakers. Withdrawal of this rejection is therefore respectfully requested.

***Rejections under 35 U.S.C. § 103***

The rejection of claim 15 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Verhaegh is respectfully traversed. As discussed above, in the enclosed Declaration, Applicant Jack Schalken states that co-authors Adrie van Bokhoven and Frank Smit performed experiments disclosed in the Verhaegh document that do not amount to an inventive contribution of the claimed invention of the present application. As stated in the Declaration, Adrie van Bokhoven and Frank Smit were technicians in Dr. Schalken's laboratory and carried out experiments under Dr. Schalken's direct supervision and control.

Thus, in light of the Declaration, Verhaegh cannot serve as a prior art reference in a rejection of the pending claims under 35 U.S.C. § 103(a). Accordingly, withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

The rejection of claim 15 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bussemakers is respectfully traversed.

As demonstrated above, Bussemakers does not teach or suggest the sequences of the present invention. Thus, Bussemakers, could not suggest a diagnostic method to assess promoter activity of the claimed promoter sequences.

In view of the above and foregoing it is respectfully submitted that the rejection of claim 15 under 35 U.S.C. § 103(a) be withdrawn.

Further, claims 10 and 13-14 depend from claims 9 and 12, respectively. Accordingly, withdrawal of the objection to claims 9, 10 and 12-14 is respectfully requested.

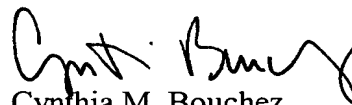
### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Date: October 29, 2004

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Enclosure

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